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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,542	11/28/2005	Martin Gagnon	4810-70826-01	3811

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,542	GAGNON ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-60* is/are pending in the application.

4a) Of the above claim(s) *33-45 and 50-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-47* is/are rejected.

7)☒ Claim(s) *27-32 and 46-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present application has been transferred from former Examiner Young to the present Examiner.

Election/Restrictions

Applicant's election without traverse of Group I, claims 27-32 and 46-49, as drawn to the peptide species, SEQ ID NO: 3, in the reply filed on 5/18/07 is acknowledged.

It is noted that former Examiner Young mistakenly meant to make the previous Restriction Requirement an election of the peptide, as an *election of the invention*, *not* an election of species. Namely, the restriction requirement is herein corrected to:

Applicant is required to select a single disclosed peptide as their invention. This is an election of invention under Section 121, 35 USC, **not** an election of species from a disclosed genus. Claims 1-27 (specifically Group I, claims 27-32 & 46-49) comprise peptides that differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. Thus, sequences without a divulged core structure that explains the peptides' functions or properties have been claimed for Inventions I – VI (the only possible core structure of these 11mers being N (X7) – Y (X8) [See formula claim 1, SEQ ID NO: 1 & 2] which is not substantial enough to constitute a reasonable core for coextensive search purposes, further in light of the base peptide being known/not novel, and thus said minor core being known as well). Therefore, the peptide sequences (SEQ ID NOS: 1-23, first two being generic) are considered to be patentably distinct. If any of Inventions I - VI is elected, it will be examined only insofar as it pertains to the single sequence listed therein and selected therefrom. This is NOT a species

election, but rather an invention election under Section 121, 35 USC. *If sequences of the other inventions happen to be found in the search of the selected invention, the examiner will rejoin the invention comprising the found sequence in accordance with in re Ochiai.* Rejoinder is possible if Applicant provides a single and specific representative subsequence (that core which must itself be deemed novel, otherwise the search of any peptides therefrom again turns upon sequence by sequence analysis and undue burden) AND states that the sequences claimed are not patentably distinct, given a disclosed unifying common feature. Applicant is informed that if the specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

This Examiner has reviewed the myriad of distinct peptides of the invention, all modified peptides of a known peptide, and absent submission by Applicant of an overlapping representative subsequence AND admission that the sequences are not patentably distinct, the election of the distinct peptide of SEQ ID NO: 3, will remain and election of the invention, and not species. Applicant may telephone the present Examiner if further clarification is desired. To which the Examiner is more than willing to discuss. As the restriction requirement has been modified/clarified, Applicant retains the right to traverse (or Petition), in response hereto.

Claims 33-55 and 50-60 are withdrawn from consideration as being drawn to non-elected subject matter. As to the elected invention of Group II, claims 27-32 and 46-49, the claims have only been examined as drawn to an elected peptide of invention, of SEQ ID NO: 3.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 46-47, the phrase "effective amount" as to granulocyte-macrophage colony-stimulating factor, is unclear? Effective amount for what? The same target of that for the GD2 peptide of SEQ ID NO: 2? For another purpose? A search of the publication for this application was undertaken, but no definition was found for this phrase.

Effective Amount

2173.05(c)

III. "EFFECTIVE AMOUNT"
The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See In re Mattison, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. In re Halleck, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. In re Fredericksen 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as "an effective amount" as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In Ex parte Skuballa, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

Claim Objections

Claims 27-32 and 46-49 are objected to because of the following informalities:

The products (peptides, pharmaceutical compositions, and commercial packages) have not been amended commensurate in scope with the elected invention of SEQ ID NO: 3.

Appropriate correction is required.

Observations

Claims 27-32 and 46-49, as drawn to the artificial synthesized peptide of SEQ ID NO: 3, are not reasonably taught or suggested by the prior art of record.

For clarity, the first recitation of the term "GD2", if possible, should recite the full name for "GD", followed by "GD" in parenth's.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 9/15/2007

MAURY AUDET
PATENT EXAMINER